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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/283,318 03/31/99 SMITH

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HM22/0126

EXAMINER

FOLEY, S

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

01/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/283,318

Applicant(s)

SMITH, JACK V.

Examiner

Shanon A. Foley

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 9, and 10 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9, and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/28/00 in paper no. 5 have been fully considered but they are not persuasive. See reasons below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 7, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 were rejected under 35 USC§112 in the Office Action dated 8/14/00 for failing to list at least one step in the method claims. A method is a process, involving one or more active steps. These claims list ingredients, but do not recite any actions. Therefore they are incomplete.

Claims 6 and 7 were rejected in the previously mentioned Office Action for failing to point out which of the method steps use the ingredients from claim 1. In addition, the Applicant has failed to respond how to prepare a test with reagent solutions "successively" in claims 6 and 7, step (a).

Claims 9 and 10, as amended, still refer to creatinine, cystatin C, or specific gravity, that "can be" used to normalize a sample. It remains unclear whether or not the claim requires a normalizing step.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Urnovitz in U.S. Patent 5,447,837.

In response to the 102(b) rejections over Urnovitz in Patent Number 5,447,837, Applicant states that Urnovitz patent uses multiple steps to complete the analysis for the presence of HIV antigens in urine or other body fluids and that the discrete areas of the Urnovitz Patent do not interact with each other. In addition, the Applicant claims that the reference does not teach a dry chemistry test strip or a lateral flow device and that the pretreatment steps employed by Urnovitz are for removing interfering substances in the sample and not for normalizing the sample as specified in the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., one step analysis of the HIV sample and that the control areas interact with each other) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As stated above, the Applicant has failed to list at least one step in the method claims 1-4. This fact combined with the open claim language leaves the claims vulnerable to a very broad

scope of interpretation. Since the Urnovitz patent teaches each and every element of what is claimed, the claims are anticipated.

Claims 1-4, as amended, are directed to a method for determining the presence of HIV antibodies in a sample of urine or other body fluids by a dry chemistry test strip **or** a lateral flow device with any of the buffers listed in claim 3 that produces a change in UV absorbance or color change. Claim 6 is directed to the same method by impregnating the absorbant carrier matrix with reagent solutions, drying the test means, dipping the test into the sample, and observing the color change.

The reference teaches a dry chemistry test strip and does not have to teach the lateral flow device as the claims are directed in the alternative language by employing the use of the word “**or**”. For cites referring to the dry chemistry test strip that detects HIV antigens by a color change using a buffer, Applicant’s attention is directed to the abstract, summary of the invention, columns 2, line 15 through column 3, line 40; column 5, line 63 through column 7, line 55; examples 1-3, columns 10-15; examples 5 and 6, columns 17-27, and claims 6-8. For the specific steps listed in claim 6, Applicant is directed to the before mentioned sites in the Patent. See especially examples 1, 2, 5, and 6. The steps are again anticipated in claim 6 of the patent, where the test strip is impregnated with different substances in different locations in step b), contacting the sample with the test strip in step c) and determining the presence of the HIV antibodies, step f.

Applicant states that the pretreatment step of the sample in the Urnovitz Patent are for removing interfering substances and has nothing to do with the measurement of urine creatinine, cystatin C, or specific gravity in claims 9 and 10 of the application. The Applicant states that the

Urnovitz Patent is not scientifically valid in view of the fact that urine concentration is directly related to HIV antibody concentration, but does not provide any evidence. In the absence of evidence, this assertion is not convincing.

Urnovitz teaches that there are interfering substances within body samples that need to be addressed before proceeding with the HIV detection method, see column 5, lines 41-column 6, line 51. Urnovitz teaches in test H, column 4, that the untreated, unconcentrated urine had as conclusive results as the conclusions drawn in tests directed to the concentrated urine and blood, which makes the object of claims 9 and 10 moot. Furthermore, pretreating a urine sample to determine concentration by creatinine, crystatin C, or specific gravity is well known in the art, admitted by the Applicant in the "first paragraph of the Comments" in the reply to the first Office Action. In addition, claims 9 and 10, as amended, recite "the sample **can be** normalized". The claims do not recite that the sample **is** normalized, and is interpreted to include any other means by which a urine sample concentration is determined. Urnovitz determined sample concentration to determine if the concentrations interfered with the results, see test H, column 24, lines 16-59. Therefore, the teachings of Urnovitz anticipate claim 9, as amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urnovitz as applied to claims 1-4, 6, and 9 above, and further in view of Huang et al.

Claim 10, originally dependent from claim 9 has been amended to depend from claim 7. As mentioned above, Urnovitz teaches in test H, column 4, that the untreated, unconcentrated urine had as conclusive results as the conclusions drawn in tests directed to the concentrated urine and blood, which makes the object of claims 9 and 10 moot.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have been motivated to combine use of a urine sample's natural ability to flow laterally from an application zone to the reaction zone by capillary action because this is a conventional assay format. Therefore, one of skill in the art at the time the invention was made would have been motivated to combine the teachings of Huang et al. in using lateral flow of the sample to migrate toward specific reaction sites on a test strip and further to a colored indicator taught by Urnovitz.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

One of ordinary skill in the art at the time the invention was made would have combined the teachings of Urnovitz and Huang et al. because the references teach established and conventional methods in the art that one would have conceived without the aid of hindsight. Applicant is directed to the teaching of Urnovitz where the reference teach teaches a "dip stick" where the technician holds the strip and dips it into the liquid specimen, see column 7, lines 29-33. Huang et al. teaches that other terminology for the lateral flow device is a "dipstick", see the first paragraph of column 1. One of skill in the art at the time the invention was made would have been fully aware that the two devices suggest each other, even though results are obtained by different methods. Urnovitz teaches that the dipstick is dipped into the sample container, while Huang et al. teaches that the dipstick can also utilize a liquids natural capillary action. Therefore, since the references obviously suggest one another, one of skill in the art at the time the invention was made would have concluded the teachings of the references obvious without hindsight.

Therefore, rejection is maintained for the reasons above, which are clearly supported by the teachings in the references.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of \$155.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing, whichever is longer, of an amendment after final

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rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance.

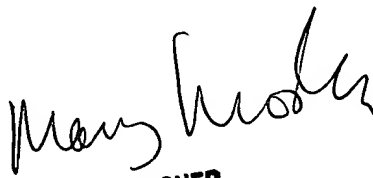
Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
January 25, 2001


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600